

REMARKS

Claims 1-8, 10-22, and 24-26 are pending in this application. Each of claims 1-8, 10-22, and 24-26 are rejected. Claims 1, 7, 10, 15, and 20-21 are amended. The claim amendments are fully supported by the as-filed specification and therefore no new matter is added with the claim amendments presented herewith. Claims 3-4, 12, 18-19, and 24 are cancelled. In view of the claim amendments and arguments presented herewith, Applicants respectfully request that the claim rejections of record be withdrawn.

I. Rejections based upon 35 U.S.C. § 102

Claims 1 and 8 are rejected under 35 U.S.C. § 102(b) as allegedly anticipated by U.S. Patent No. 5,843,050 to Jones et al. ("Jones"). Applicants respectfully traverse. Jones does not disclose or suggest all of the limitations of amended independent claim 1, let alone claim 8 dependent therefrom. For example, Jones does not disclose or suggest a cannula with a distal portion which comprises a spiral cut along a longitudinal axis of the cannula, wherein the cannula is defined from a continuum of material, and a tool disposed proximate the distal portion of the cannula that is defined from the continuum of material.

In contrast, Jones discloses a microcatheter (10) that includes a lumen (22) defined by a tubular element (30). A jacket (38) and spring (34) each surround a portion of the tubular element (30). Jones discloses that portions of each of the tubular element (30) and jacket (38) may be provided with a spiral cut. See col. 5, ll. 19-36; col. 6, ll. 25-34. Jones does not disclose or suggest that a tool may be provided upon or defined from the continuum of material as the spiral cut portion of the cannula. Because Jones does not disclose or suggest all of the limitations of claim 1, let alone dependent claim 8, Applicants respectfully request that this rejection be withdrawn.

II. Rejections based upon 35 U.S.C. § 103(a)

A. Rejections based upon Jones

Claims 2, 5, 6, 15-17, 22, and 25-26 are rejected under 35 U.S.C. § 103(a) as allegedly being obvious in view of Jones. Applicants respectfully traverse. As discussed above in section I, Jones does not disclose or suggest all of the limitations of independent claim 1. Accordingly, Jones similarly not render claims 2, 5, and 6 obvious, each of which ultimately depend from independent claim 1. Applicants respectfully request that this rejection be withdrawn.

Jones additionally does not disclose or suggest all of the limitations of independent claim 15, let alone claims 22 and 25-26 dependent therefrom. Jones does not disclose or suggest a cannula with a distal portion with a spiral cut, wherein the proximal and distal portions are defined from a continuum of metal, and a grasping portion disposed proximate the distal portion and defined from the continuum of metal. In contrast, Jones discloses a microcatheter (10) that includes a lumen (22) defined by a tubular element (30). A jacket (38) and spring (34) each surround a portion of the tubular element (30). Jones discloses that portions of each of the tubular element (30) and jacket (38) may be provided with a spiral cut. See col. 5, ll. 19-36; col. 6, ll. 25-34. Jones discloses that the tubular element is made from flexible polymers, such as PTFE (see col. 5, ll. 15-16; col. 6, ll. 41-42) and that the jacket is extruded from polyester, nylon, braided materials, or braid containing materials, such as polyimide, polyester, or nylon. See col. 6, ll. 14-17. A second embodiment of a microcatheter (48), shown in FIG. 4, that includes a liner (56) with a spiral cut and is formed from similar polymer materials, such as PTFE, TFE, fluoropolymer, HDPE, etc. See col. 8, ll. 23-26, 48-55.

Jones does not disclose that the components of the disclosed microcatheter could be made from metal. Indeed, any modification of Jones to make Jones' microcatheter from metal would destroy the intended purpose of Jones, i.e. to provide optimal flexibility to allow the microcatheter to traverse small tortuous vessels within the anatomy. See col. 1, ll. 17-52.

Additionally, Jones' microcatheter does not include a tool disposed thereon, let alone one defined from a continuum of metal with the spiral cut portion of the device.

The spiral cut portions (i.e. tubular element (30), tubular jacket (38), liner (56), etc.) of Jones' embodiments are each surrounded by a heatshrunk outer tubular jacket (42, 66) that extends beyond the distal end of the device and each spiral cut portion. See col. 6, ll. 36-44 (tubular jacket (42) extends about 1 centimeter beyond the distal end of the tubular element); col. 9, ll. 25-30 (outer jacket (66) extends distally beyond the distal terminus (62) of the liner (56)). Because each microcatheter includes a heatshrunk jacket extending from the distal end of the device, there would be no reason to apply a tool to the distal end thereof, much less a tool that was defined from a continuum of metal with the spiral cut portion of the device, without hindsight review of the subject as-filed specification. Any tool disposed upon the distal end of Jones' device would be surrounded by the heatshrunk jacket portion and therefore would not effectively interact with any foreign material proximate the distal end of the device. Any modification of Jones to provide a tool proximate the distal portion thereof would be improper because it would not be functional due to the contrary disclosure of Jones' heatshrunk outer jacket. Because Jones does not disclose or suggest all of the limitations of independent claim 15, let alone the claims dependent therefrom, Applicants respectfully request that this rejection be withdrawn.

B. Rejections based upon Jones and Sachdeva

Claims 3, 4, 7, 12-14, 18-21, and 24 are rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Jones in view of U.S. Patent No. 5,885,258 to Sachdeva et al. ("Sachdeva"). Claims 3, 4, 9, 12, 18-19, and 24 are cancelled. Applicants respectfully traverse because the combination of Jones and Sachdeva does not disclose or suggest all of the limitations of each of independent claims 1 and 15, let alone claims 7, 13-14, and 20 ultimately dependent therefrom. Specifically, there is no *prima facie* case of obviousness of the dependent claims recited above (as well as independent claims 1 and 15, which have been amended to include the limitations of previously rejected dependent claims under this combination) because Sachdeva does not disclose all of the limitations missing from Jones and vice versa, and there is no reason to modify the devices disclosed in each reference with features from the other reference.

Sachdeva discloses a basket (14) disposed on an end of a shape metal tube (11). The basket (14) may be formed from four slots (12) disposed near the distal end of Sachdeva's tube (11). *See* col. 3, ll. 34-44. Sachdeva's tube is formed from a material with shape metal properties to allow the basket to be manipulated between extended and restricted positions (as best viewed in FIGs. 1A-1D) both with an external delivery tube (13) that can selectively compress or release the arms of the basket (14), and due to changes in temperature of the arms of the basket (14), which causes a change in the orientation of the arms of Sachdeva's tube (11) due to the intrinsic shape memory properties of the material forming the basket (14).

As discussed above, Jones does not disclose or suggest a cannula that is defined from a continuum of material (or metal as in independent claim 15) that includes a tool disposed proximate the distal portion of the cannula. There is no reason to modify Jones to include the tool or grasper made from "memory metal" disclosed in Sachdeva. Initially, Jones discloses that the components that form the microcatheter may be made from several types of polymers, such as PTFE, high density polyethylene, among others. *See* col. 6, ll. 35-44, col. 12, ll. 22-42. One of ordinary skill in the art would appreciate that polymers are not suitable for forming a tool therefrom because they are not sufficiently rigid and strong to perform the desired task for the tool.

Further, Jones' catheter is directed to use in small tortuous vessels, such as those found in the soft tissue of the brain and liver, and Jones emphasizes that the disclosed catheter "must also exhibit optimal flexibility, while at the same time maintaining adequate column strength ..." (col. 1, ll. 23-25; *See also* col. 1, ll. 42-52). Because Jones repeatedly emphasizes the requirement that the Jones catheter be sufficiently flexible to navigate through many narrow tortuous paths in the anatomy, any modification of Jones' disclosed structure to a stiffer and stronger material (such as shape metal) to allow for a tool to be defined from a continuum of material (metal) with the spiral cut portion of the device would make the modified microcatheter unsuitable for its intended purpose because it would no longer be configured to navigate through the intended tortuous paths within the anatomy. This modification would be improper.

See *McGinley v. Franklin Sports, Inc.*, 262 F.3d 1339, 1353-1354 (Fed. Cir. 2001); *Coming Glass Works v. Sumitomo Electric U.S.A. Inc.*, 868 F.2d 1251, 1262 (Fed. Cir. 1989) (modifications that destroy the purpose of the prior art are not permitted).

Accordingly, one of ordinary skill in the art would not have had a reason to modify Jones as would be necessary to provide a tool proximate the distal end of the device that is formed from a continuum of material (metal) with the spiral cut distal portion of the device without improper hindsight review of the as-filed specification.

Moreover, the spiral cut portions (i.e. tubular element (30), tubular jacket (38), liner (56), etc.) of Jones' disclosed devices are each surrounded by a heatshrunk outer tubular jacket (42, 66) that extends beyond the distal end of the device an each spiral cut portion. See col. 6, ll. 36-44 (tubular jacket (42) extends about 1 centimeter beyond the distal end of the tubular element); col. 9, ll. 25-30 (outer jacket (66) extends distally beyond the distal terminus (62) of the liner (56)). Because each microcatheter includes a heatshrunk jacket extending from the distal end of the device, there would be no reason to apply a tool to the distal end thereof, much less a tool that was defined from a continuum of material (metal) as the spiral cut portion of the device, without hindsight review of the subject as-filed specification. Any tool disposed upon the distal end of Jones' device would be surrounded by the heatshrunk jacket portion and therefore would not effectively interact with any foreign material proximate the distal end of the device. A combination of Jones and Sachdeva in view of this contrary disclosure in Jones (as well as the differences in disclosed materials necessitated by Jones and Sachdeva's designs and objectives) could only be made by improperly failing to interpret each reference as whole including the portions teaching away from the proposed combination.

Similarly, there is no reason to modify Sachdeva's memory metal tube (11) to include a spiral cut along the longitudinal axis thereof without improper hindsight reference to the as-filed specification. Because each independent claim requires that both the portion of cannula with the spiral cut and the portion of the cannula with the tool be formed from a continuum of material (metal), the combination of Jones and Sachdeva cannot be reasonably asserted to render independent claims 1 and 15

obvious, let alone the claims dependent therefrom. Accordingly, Applicants respectfully request that this rejection be withdrawn.

C. Rejections based upon Jones, Sachdeva, and DeCastro

Claims 10, 11, and 20 are rejected under 35 U.S.C. § 103(a) as allegedly being obvious over the combination of Jones and Sachdeva as applied and discussed above, in further view of U.S. Patent No. 4,899,733 to DeCastro et al. ("DeCastro"). Applicants respectfully traverse because the addition of DeCastro does not provide the limitations of independent claims 1 and 15 missing from the combination of Jones and Sachdeva (as well as the missing reason to combine these references). Because this combination of references does not disclose or suggest all of the limitations of independent claims 1 and 15, let alone claims 10, 11, and 20 dependent therefrom, Applicants respectfully request that this rejection be withdrawn.

Pending claims 1-2, 5-11, 13-17, 20-23, and 25-26 are patentable. Applicants respectfully request that the pending rejections of the claims of this application be withdrawn. The undersigned attorney can be reached at (312) 222-8124 if a teleconference would expedite this application.

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